UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,025	03/05/2007	Marianna Foldvari	58152-8001.US00	2769

22918 7590 10/14/2009

PERKINS COIE LLP
P.O. BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,025	FOLDVARI ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 20-23* is/are pending in the application.

4a) Of the above claim(s) *11 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/07;6/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 20-23 are pending in the present application.

Applicant's election without traverse of Group I in the reply filed on 9/17/09 is acknowledged. Applicants further elected the following species: (a) a gemini cationic surfactant; (b) a cream and (c) DOPE.

Therefore, claims 11 and 20-23 were withdrawn from further consideration because they are directed to non-elected invention and non-elected species.

Claims 1-10 are examined on the merits herein with the above elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Camilleri et al (WO 99/29712; IDS).

Camilleri et al (WO 99/29712; IDS) already disclose at least a mixture of peptide-based Gemini compounds and polynucleotides (e.g., DNA, RNA and plasmid vector) for gene therapy and genetic immunization in whole organisms as well for transfection of

polynucleotides in cells in culture (pages 5-6; examples 17-19). The peptide-based Gemini compounds comprise positively charged hydrophilic heads and hydrophophic tails of C(10-20) saturated or unsaturated alkyl groups (see at least page 2, line 15 continues to line 7 of page 5). Camilleri et al further disclose specifically that the gemini compound may be used in combination with one or more supplements to increase the efficiency of transfection, and the supplements include a neutral carrier such as dioleyl phosphatidylethanolamine or DOPE (page 5, lines 21-26). In exemplifications, such mixtures comprising of peptide-based Gemini compounds and polynucleotides are in a serum-free solution medium (see at least examples 17-19).

Since the mixtures of Camilleri et al have at least the same components and form as a topical delivery system as broadly written and claimed, the teachings of Camilleri et al meet every limitation of the instant claims.

Additionally, please, also note that where, as here, the claimed and prior art products are identical **or** substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Wheeler, C (US 6,696,424).

Wheeler already teaches a composition comprising a novel cationic lipid compound having hydrophobic tails and two quarternary ammonium headgroups bridged by a linker that is useful for facilitating delivery and transfection of biologically active agents such as DNA (e.g., plasmid DNA) into cells (see at least Summary of the Invention and the abstract). The cationic lipid compounds have general formula (I) and (II), with R1, R2, R3 and R4 are C1 to C24 alkyl or alkenyl; and R5, R6, R7 and R8 are C1 to C10 alkyl or alkenyl (see col. 6; col. 8; and Figures 1A-1B). These cationic lipid compounds fall within the scope of a gemini cationic surfactant; and please note that the term "Gemini surfactant" means a surfactant molecule which contains more than one hydrophobic tail as defined by the instant specification on page 4, lines 16-17. Wheeler also disclose an immunogenic composition comprising a nucleotide sequence that encodes an immunogen (one or more multiple plasmids) and the composition comprising a novel cationic lipid compound having hydrophobic tails and two quarternary ammonium headgroups briddged by a linker to treat viral, bacterial, fungal and parasitic infectious diseases; and the immunogenic composition further includes one or more co-lipids or other lipid aggregate-forming components such as phospholipids, lysophopholipids, lyso lipids and cholesterol (col. 3, line 44 continues to line 19 of col. 4; col. 11, lines 55-59). Moreover, the immunogenic composition can also

be in the form of topical skin creams (see at least col. 14, line 44 continues to line 16 of col. 17).

Since the immunogenic composition of Wheeler has the same components and form as a topical delivery system as broadly written and claimed, the teachings of Wheeler meet every limitation of the instant claims.

Additionally, please, also note that where, as here, the claimed and prior art products are identical **or** substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (US 6,696,424) in view of Weiner et al (US 5,981,505).

Wheeler already teaches a composition comprising a novel cationic lipid compound having hydrophobic tails and two quarternary ammonium headgroups bridged by a linker that is useful for facilitating delivery and transfection of biologically active agents such as DNA (e.g., plasmid DNA) into cells (see at least Summary of the Invention and the abstract). The cationic lipid compounds have general formula (I) and (II), with R1, R2, R3 and R4 are C1 to C24 alkyl or alkenyl; and R5, R6, R7 and R8 are C1 to C10 alkyl or alkenyl (see col. 6; col. 8; and Figures 1A-1B). These cationic lipid compounds fall within the scope of a gemini cationic surfactant; and please note that the term "Gemini surfactant" means a surfactant molecule which contains more than one hydrophobic tail as defined by the instant specification on page 4, lines 16-17. Wheeler also disclose an immunogenic composition comprising a nucleotide sequence that encodes an immunogen (one or more multiple plasmids) and the composition

comprising a novel cationic lipid compound having hydrophobic tails and two quarternary ammonium headgroups briddged by a linker to treat viral, bacterial, fungal and parasitic infectious diseases; and the immunogenic composition further includes one or more co-lipids or other lipid aggregate-forming components such as phospholipids, lysophopholipids, lyso lipids and cholesterol (col. 3, line 44 continues to line 19 of col. 4; col. 11, lines 55-59). Moreover, the immunogenic composition can also be in the form of topical skin creams (see at least col. 14, line 44 continues to line 16 of col. 17).

Wheeler does not teach specifically an immunogenic composition comprising a plasmid vector comprising a gene coding for interferon-γ.

However, at the effective filing date of the present application Weiner et al already taught at least an immunogenic composition comprising nucleotide sequences that encode a target protein and further include genes for proteins that enhance the immune response against such target proteins; and examples of such genes include those which encode interferon-γ, GM-CSF, IL-2, IL-12 (see at least Summary of the Invention and particularly col. 7, lines 54-65)..

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the immunogenic composition of Wheeler by also including a plasmid vector construct comprising a gene coding for interferon-γ in light of the teachings of Weiner et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because Weiner et al already taught specifically that the further inclusion of

genes such as those which encode interferon-γ, GM-CSF, IL-2, IL-12 in an immunogenic composition to enhance the immune response against targeted proteins.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Wheeler and Weiner et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 12/215,963.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-38 of copending Application No. 12/215,963 are drawn to a delivery system for a biologically active agent comprising a Gemini surfactant or an asymmetric Gemini surfactant in admixture with a biologically active agent.

The claims of the present application differ from the claims of the copending Application No. 12/215,968 in reciting specifically "a topical delivery system".

The claims of the present application can not be considered to be patentably distinct over claims 1-38 of copending Application No. 12/215,963 when the copending Application disclosed specifically that the delivery system is in the form of creams, lotions, pastes, ointments, gels and liquids for topical applications to skin or mucosal membrane (see at least pages 23-25). Accordingly, the claims of the copending Application fall within the scope of claims 1-4 and 6-10 of the present application.

This is because it would have been obvious to an ordinary skilled artisan to modify the claims of the copending Application to fall within the scope of claims in the present application because the above specific embodiment is explicitly disclosed or taught in the copending Application No. 12/215,963 as a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Fan et al. (Nature Biotechnology 17:870-872, 1999) teach immunization via hair follicles by topical application of naked DNA to normal skin.

2. Shi et al (Vaccine 17:2136-2141, 1999) teach DNA-based non-invasive vaccination onto the skin using at least liposome-complexed plasmid DNA onto the outer layer of skin to elicit an immune response against the protein encoded by the DNA.

3. Domashenko et al (Nature Biotechnology 18:420-423, 2000) teach a topical delivery of transgenes to hair follicles for treating disorders of the skin and hair using liposome-DNA mixture or lipoplex.

4. Kwetkat et al (US 6,710,022; IDS) disclose surfactant compositions of Gemini surfactants and co-amphiphiles as dispersants in therapeutic prparations in the forms of creams or lotions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/
Primary Examiner, Art Unit 1633